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10/525,020	02/18/2005	Kazuo Yamamoto	081356-0233	6071

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EXAMINER	
LIU, SUE XU	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,020	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21* is/are pending in the application.

4a) Of the above claim(s) *19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14-21* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20060222* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-13 have been canceled as filed on 6/13/2005.

Claims 14-21 have been added and are currently pending as filed on 6/13/2005.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 14-18, drawn to eukaryotic cells comprising heterologous DNA coding for a cargo receptor.

Group 2, claim(s) 19 and 20, drawn to a method for producing a glycoprotein.

Group 3, claim(s) 21, drawn to a method for screening for a test substance.

2. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

a. The common technical feature in Group 1 is eukaryotic cells expressing a cargo receptor.

b. The common technical feature in Group 2 is a method for producing a glycoprotein.

c. The common technical feature in Group 3 is a method for screening for a test substance.

Therefore, Groups 1-3 are not so linked by the same or a corresponding special technical feature as to form a single inventive concept. In addition, the special technical feature of Group 1 is known in the prior art. Appenzeller et al (Nature Cell Biology. Vol. 1: 330-334; 10/1999) teach a eukaryotic cell (Lec1 cells) expressing mutant ERGIC-53 (a cargo receptor). (See Methods section on Page 334 of the reference). Thus, the inventions lack unity.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants are requested to further elect **a single ultimate species for <u>each</u>** of the following:

a. A single specific cargo receptor.

b. A single specific glycoprotein.

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Thus the unity of invention between each species subgroup is lacking.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are distinct, each from the other structurally and functionally, because their modes of action are different. Therefore, the species have different issues regarding patentability and represent patentable distinct subject matter.

Applicants' Election of Invention

4. During a telephone conversation with Applicants' representative, Ms. Yang Tang on 2/21/2006, a provisional election was made with traverse to prosecute the invention of Group 1, claims 14-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicants elected with traverse of Group 1 (Claims 14-18) as described supra. The traversal is on the ground(s) that the cited prior art does not teach the technical feature for Group

1. This is not found persuasive because the technical feature of Group 1 does not constitute as a special technical feature as defined by PCT Rule 13.2. The different groups of invention do not share a common special technical feature as discussed above. In addition, the assumed linking technical feature of Group 1 claims is a cell comprising a cargo receptor, which is known in the prior art. Ueno et al (Nihon Yakugakkai Dai 121 nenkai Yoshishu, Page 7; Issued on March 5, 2001; Abstract for a meeting of the Pharmaceutical Society of Japan) teach cells expressing cargo receptor with mutations in the carbohydrate binding domain.

6. Applicants elected with traverse of the following species:

A.) ERGIC-53;

B.) membrane bound protein,

as communicated during the telephone conversation on 2/21/2006. On 3/1/2006, applicants changed the species election for A.) from ERGIC-53 to VIP36 (see the attached Interview Summary). Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the nonelected species are withdrawn from each corresponding claim.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Claims 1-13 have been cancelled;

Claims 14-21 are currently pending;

Claims 19-21 have been withdrawn;

Claims 14-18 are being examined in this application.

Priority

10. This application is filed under 35 U.S.C 371 of PCT/JP03/01718 (filed on 02/18/2003).

Receipt is acknowledged of papers (Foreign application: JAPAN 2002-238559; filed on 8/19/2002) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Drawings

11. The drawings/figures (Specifically Figure 3) are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Appropriate correction is required.

Sequence Rule Compliance

12. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) below:

The instant disclosure recites lists of sequences (e.g. Page 79, Figure 3, etc.), which are identified by sequence names and are NOT in compliance with Sequence Rule. Reference to sequences in both specification and claims must be accompanied by proper sequence identifier, i.e. SEQ ID Nos. Applicants are requested to amend the instant specification and claims accordingly.

Specification

13. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

15. Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims briefly recite a product of eukaryotic cells comprising heterologous DNA coding for cargo receptors with alterations of the said cargo receptors' carbohydrate recognition domain. The said eukaryotic cells have intended use of expressing glycoprotein with a modified carbohydrate moiety or a particular glycoform. The instant claims further recite a plurality of eukaryotic "cells together express a variety of carbohydrate recognition domains of a cargo receptor," which could be interpreted to mean cells expressing additional carbohydrate recognition domains in addition to the heterologous DNA recited in Claim 14.

To satisfy the written description requirement, applicants may convey reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

Applicants may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

Written description requirement of 35 U.SC. 112 exists independently of enablement requirement, and the requirement applies whether or not case involves question of priority, since requirement applies to all inventions including chemical inventions, and since the fact that the patent is directed to method entailing use of compound, rather than to compound per se, does not remove patentee's obligation to provide description of compound sufficient to distinguish infringing methods from non-infringing methods. See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ 2d 1886, 1890-93 (Fed. Cir. 2004).

With regard to the description requirement, applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it form other materials." University of California v. Eli Lilly and Co., 43

USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original) [The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical an/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F. 3d at 1568, 43 USPQ2d at 1406.

As discussed above, the instant claim could be interpreted to mean that a plurality of eukaryotic cells comprising a heterologous DNA coding for a modified cargo receptor as well as a variety of carbohydrate recognition domains of a cargo receptor. Nowhere in the instant disclosure was this composition described. The instant specification recites examples of cells comprising only one type of heterologous cargo receptor. Therefore, the instant specification and/or claim do not convey possession of the claimed plurality of cells.

In addition, the instant claim recites the expression of a glycoprotein with a modified carbohydrate moiety. The specification and/or the claim do not identify a wild-type glycoprotein from which the carbohydrate moiety could be modified. Without the possession or the identity of the wild-type glycoprotein, the recited modification could not be feasible or known by an ordinary skilled artisan.

Although the instant specification recites examples of eukaryotic cells, cargo receptor (e.g. ERGIC-53 and VIP36), and glycoprotein, the instant specification and/or the aforementioned claims do not provide adequate written description to show possession of the

entire genus of eukaryotic cells, the entire genus of cargo receptor, and the entire genus of glycoprotein. The instant specification discloses "cargo receptor" as a general nomenclature for animal lectins playing important roles in quality control and sorting of glycoproteins" ([0042] page 2 of the spec.), which does not provide sufficient structural and/or functional limitations for the entire genus of cargo receptor. In addition, the recited genus of "glycoprotein" is also not structurally or functionally defined such that a common structure (e.g. amino acid sequence) and/or function is disclosed to show possession of the genus. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus eukaryotic cells, genus of cargo receptor, and genus of glycoprotein. Adequate written description requires more than a mere statement that it is part of the invention and reference to a possibility of creating it, regardless of the complexity or simplicity of the method of creating such composition. The composition itself is required.

Therefore, the instant Claims 14-18 do not meet the written description provision of 35 U.S.C. 112, first paragraph.

16. The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrases "an alteration of its carbohydrate" and "modified carbohydrate moiety", which are indefinite. The term "modified" is not defined in the specification or the claim, and the term could mean a variety of different modifications. The definition provided in the instant specification is vague and does not provide a clear guideline for the term "alteration", which could mean various modifications including amino acid mutations, posttranslational modification, amino acid deletions, chemical modification, etc. Without a clear definition, a skilled artisan would not be able to define the metes and bounds of the claimed invention.

Claim 14 recites the limitation "said cells". There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the phrase a plurality of eukaryotic "cells together express a variety of carbohydrate recognition domains of a cargo receptor," which could be interpreted to mean cells expressing additional carbohydrate recognition domains in addition to the heterologous DNA recited in Claim 14. The claim would direct to two different compositions with one reads on cells comprising one heterologous cargo receptor, and another reads on cells comprising one heterologous cargo receptor and additional carbohydrate recognition domains. This renders the claim indefinite.

Claim 17 recites the limitation "said cells". There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "a particular glycoform", which is indefinite. Neither the instant specification nor the claim defines the specific glycoform that is characteristic of the glycoprotein.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 14, and 16-18 are rejected under **35 U.S.C. 102(b)** as being anticipated by Ueno et al (Nihon Yakugakkai Dai 121 nenkai Yoshishu, Page 9; Issued on March 5, 2001; Abstract for a meeting of the Pharmaceutical Society of Japan).

The instant claims briefly recite a product of eukaryotic cells comprising heterologous DNA coding for cargo receptors with alterations of the said cargo receptors' carbohydrate recognition domain. The said eukaryotic cells have intended use of expressing glycoprotein with a modified carbohydrate moiety or a particular glycoform, and enriching for cells expressing glycoprotein with a particular glycoform.

Ueno et al teach generation of eukaryotic cells (mammalian cells) comprising ERGIC-53 with altered lectin domains (carbohydrate binding domains). (See the entire abstract) The reference teaches the ERGIC-53 cDNA was altered at its lectin domain (would read on alteration of its carbohydrate recognition domain). (See 2nd paragraph of the reference.) The reference

further teaches the said ERGIC-53 cDNA was inserted into a plasmid and expressed in mammalian cells (would read on eukaryotic cell comprising heterologous DNA coding for a cargo receptor). (See 2nd paragraph) The reference also teaches that various alterations to the lectin domain were created and that "various recombinants ERGIC-53" were transfected into mammalian cells to "obtain various cell lines" (2nd paragraph), which would read on a plurality of eukaryotic cells expressing a variety of carbohydrate recognition domains. The reference further teaches that "a glycoprotein having distinctive glycoform was observed in some of the recombinants ERGIC-53" (see 3rd paragraph), which would read on eurkaryotic cells expressing glycoprotein with a particular glycoform.

Thus, the reference clearly anticipates the claimed invention.

20. Claims 14-18 are rejected under **35 U.S.C. 102(b)** as being anticipated by Hirai et al (Nihon Yakugakkai Dai 121 nenkai Yoshishu, Page 7; Issued on March 5, 2001; Abstract for a meeting of the Pharmaceutical Society of Japan).

The instant claims briefly recite a product of eukaryotic cells comprising heterologous DNA coding for cargo receptors with alterations of the said cargo receptors' carbohydrate recognition domain. The said eukaryotic cells have intended use of expressing glycoprotein with a modified carbohydrate moiety or a particular glycoform.

Hirai et al teach the generation of recombinant VIP36 containing cells (See the entire document). The reference teaches that the lectin domain (carbohydrate binding domain) of VIP36 (cargo receptor) was recombined with BPA lectin and MAH lectin (would read on a variety of carbohydrate recognition domain and alteration of the said domain). The reference

also teaches the cells used to express the recombinant VIP36 mutants are MDCK cells (would read on a eukaryotic cells). The reference further teaches observing "the structural and functional changes in sugar chains of glycoproteins to be biosynthesized" in the cells comprising the altered carbohydrate recognition domain (See 1st paragraph), which would read on the intend use of expressing glycoprotein with modified carbohydrate moiety. In addition, the reference teaches that the cells having the different chimeric or recombinant cargo receptor expressed therein specific types of sugar chains of intracellular and extracellular glygoproteins (See last paragraph), which would read on a plurality of cells expressing glycoprotein with a particular glycoform. Furthermore, the reference teaches the intracellular and extracellular localization of the expressed glycoprotein using FACS analysis, which would read on membrane-bound or secretory protein.

Thus, the reference clearly anticipates the claimed invention.

21. Claims 14-18 are rejected under **35 U.S.C. 102(a)** as being anticipated by Sato (Summary of Master's Thesis, Graduate School of Frontier Science, Dept. of Integrated Biosciences, The University of Tokyo, Page 22-23; 2/18/2002).

The instant claims briefly recite a product of eukaryotic cells comprising heterologous DNA coding for cargo receptors with alterations of the said cargo receptors' carbohydrate recognition domain. The said eukaryotic cells have intended use of expressing glycoprotein with a modified carbohydrate moiety or a particular glycoform, and enriching for cells expressing glycoprotein with a particular glycoform.

Sato teaches the eukaryotic cells comprising random mutation in the carbohydrate recognition domain of VIP36 (cargo receptor). The reference teaches establishing cell lines that display modified oligosaccharides (carbohydrates) and modified glycosylation of glycoprotein on the plasma membrane of MDCK cells (See 1st paragraph on Page 22 of the reference), which would read on cell expressing glycoprotein (that is membrane bound) with modified carbohydrate moiety. The reference also teaches the transfected cells (containing the genes encoding mutant VIP36) are sorted and enriched by magnetic sorting based on the expressed glycoprotein (See 1st paragraph, Page 23).

Thus, the reference clearly anticipates the claimed invention.

22. Claims 14-18 are rejected under **35 U.S.C. 102(a)** as being anticipated by Shimauchi (Summary of Master's Thesis, Graduate School of Frontier Science, Dept. of Integrated Biosciences, The University of Tokyo, Page 3-7; 2/18/2002).

The instant claims briefly recite a product of eukaryotic cells comprising heterologous DNA coding for cargo receptors with alterations of the said cargo receptors' carbohydrate recognition domain. The said eukaryotic cells have intended use of expressing glycoprotein with a modified carbohydrate moiety or a particular glycoform, and enriching for cells expressing glycoprotein with a particular glycoform.

Shimauchi teaches modifying carbohydrate recognition domains of ERGIC-53 (2nd paragraph, Pg 3 of the reference). The reference teaches that ERGIC-53 is a cargo receptor with carbohydrate recognition domain (page 3, 2nd para.). The reference also teaches randomly mutating the carbohydrate recognition domains and transfected into MDCK cells (1st paragraph,

Page 4), which would read on eukaryotic cells comprising heterologous DNA coding for cargo receptor with altered carbohydrate binding domains. The reference further teaches that the various transfected cells express glycoproteins with various glycoforms on the cell surface (would read on membrane bond protein; See 1st para. Page 4). In addition, the reference teaches the eukaryotic cells with mutated ERGIC library were sorted based on the displayed carbohydrate moieties by using specific lectins (2nd and 3rd paras. Page 5; 2nd para. Page 6), which would read on enriching for eukaryotic cells that express glycoprotein with particular glycoforms.

Thus, the reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 14, and 16-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Itin et al (Molecular Biology of the Cell. Vol. 7: 483-493; March 1996).

The instant claims briefly recite a product of eukaryotic cells comprising heterologous DNA coding for cargo receptors with alterations of the said cargo receptors' carbohydrate recognition domain. The said eukaryotic cells have intended uses or inherent properties of

expressing glycoprotein with a modified carbohydrate moiety or a particular glycoform, and enriching for cells expressing glycoprotein with a particular glycoform.

Itin et al teach modifying the carbohydrate binding region of ERGIC-53 and overexpressing the modified lectin in cells (see Abstract of the reference). The reference teaches that the modified protein is overexpressed in COS-1 cells (read on eukaryotic cells; See page 485 left col. 2nd paragraph). The reference also teaches several ERGIC-53 expression constructs with amino acid mutations in the carbohydrate binding domain were inserted in cells (page 487, right col. 3rd para.), which would read on a plurality of cells comprising a variety of carbohydrate recognition domains of a cargo receptor.

The reference does not specifically teach the claimed composition's intend uses or inherent properties of "expresses a glycoprotein with a modified carbohydrate moiety", and "enriched for eukaryotic cells that express glycoprotein characterized by a particular glycoform". However, the claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. That is the composition of eukaryotic cells expressing a cargo receptor with modified carbohydrate binding region appears to the same as the composition taught by the reference. The phrases of "expresses a glycoprotein with a modified carbohydrate moiety" and "enriched....a particular glycoform" appear to be an inherent property of the eukaryotic cell as the result of expressing the claimed modified cargo receptor. The phrases of "expresses a glycoprotein with a modified carbohydrate moiety" and "enriched....a particular glycoform" could also be interpreted as intended use for the claimed composition. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant

application versus the reference. That is whether or not the cells taught by the reference expresses a glycoprotein with a modified carbohydrate moiety or the cells express glycoprotein with a particular glycoform. In the absence of the evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1992(PTO Bd. Pat. App. & Int. 1989).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
2/23/2006

PADMASHRI PONNALURI
PRIMARY EXAMINER